

Appl. No. : 09/995,917
Filed : November 27, 2001

REMARKS

Applicant affirms the election of Group I, Claims 1-23 and 27-28, which was provisionally elected in a telephone conference with the Examiner on August 13, 2002. Claims 24-26 were withdrawn as being drawn to a nonelected invention. Applicants thank the Examiner for the indicated allowability of Claims 6, 7, 14, 23, 27 and 28. Claims 4, 9-11, and 18-20 are cancelled by this amendment and Claims 29-31 have been added. Thus, Claims 1-3, 5-8, 12-17, and 21-31 remain presented for examination.

Specification

The Examiner objected to the presence of an embedded hyperlink in the specification at page 36, line 4 of the originally filed specification. Applicants submit herewith a replacement paragraph wherein the portion "www." of the hyperlink has been removed. Thus, this reference is no longer an active hyperlink or other form of browser-executable code. For this reason, Applicants respectfully request withdrawal of this objection.

Discussion of Rejections under 35 U.S.C § 112, Second Paragraph

Claims 1-3, 5, 8, 12-13, 15-17, and 21-23 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected Claim 1, alleging that the metes and bounds of "DAS5" have not been defined. Applicants traverse this rejection, and note that the "DAS5" protein is described in detail in the specification. For example, at page 5, beginning on line 9, Applicants describe features of the DAS5 protein, including the fact that it is a member of the P450 family of proteins and includes well-known conserved domains. One example of a DAS5 protein is shown as SEQ ID NO: 1. One of ordinary skill in the art would understand the meets and bounds of this term by reference to the specification and sequence listing.

However, solely in order to advance prosecution of this application, Applicants have amended Claim 1 to recite a "polypeptide having at least 95% sequence identity to SEQ ID NO:

1". Support for the amended language can be found in the specification at, for example, page 8, line 29 through page 9, line 7.

Claim 1 was additionally rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential step. The Examiner alleged that Claim 1 requires a step of allowing the nucleic acid to be expressed. Applicants disagree, as that step would occur inherently following transformation of the plant cell. However, in order to advance prosecution, Applicants have added the step of "allowing said nucleic acid to be expressed," to Claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner also alleged that the metes and bounds of Claims 1, 8, and 17 were unclear for the recitation of "increased size". Applicants assert that one of ordinary skill in the art would understand that a plant with an "increased size" meant a plant that had become larger by any means of measurement. As is well known, indicators of increased size include plant height, plant mass, and plant yield. However solely to advance prosecution, Applicants have amended Claims 1, 8 and 17 to recite a method of increasing plant "yield", which is defined at page 8, lines 2-6 as increased plant growth, increased crop growth and/or increased biomass production. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner alleged that the metes and bounds of "gamete producing cells" and "cells which regenerate into whole plants" in Claim 4 was unclear. This claim has been cancelled, thus obviating this rejection.

The Examiner rejected Claims 8-11 and 17-20 for use of the term "homology". Applicants respectfully traverse. The term homology is well-known to those of ordinary skill in the art to mean "corresponding or similar in position, value, structure, or function" (The American Heritage® Dictionary of the English Language, Fourth Edition). Moreover, the specification contains a detailed explanation of calculating homology using well-known programs, such as BLAST. See page 9, beginning with line 21. Accordingly, the metes and bounds of this term are clear, and Applicants respectfully request withdrawal of this rejection.

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As requested by the Examiner, Applicants have amended Claims 12 and 21 to indicate that the exogenous nucleic acid is “operably” linked to the promoter. This amendment was made solely to clarify that the exogenous nucleic acid is functionally linked to the promoter.

The Examiner requested that the word “sequence” be inserted after the word “acid” in dependent Claims 13 and 22. However, Applicants have removed this term from the corresponding independent Claims 8 and 17, thus obviating this rejection.

Discussion of Written Description Rejections under 35 U.S.C § 112, First Paragraph

Claims 1-3, 5, 8, 12, 15-17, and 21 were rejected under 35 U.S.C. 112, first paragraph because the specification allegedly did not provide a sufficient written description of the claimed invention. Applicants respectfully disagree.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). According to the Federal Circuit, it is clear that an Applicants need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

The Examiner argued that Applicants did not disclose any specific structural, physical, or chemical properties for the DAS5 protein. However, this is simply untrue. For example, Applicants describe the detailed structure of one example of a DAS5 gene in SEQ ID NO: 1. In addition, page 5, line 20 begins a discussion of the structural features of the DAS5 protein. The DAS5 protein is described as being a member of the P450 family of proteins having characteristic conserved domains such as an N-terminal membrane-anchoring domain, a proline rich domain, a heme-binding domain and an oxygen-binding domain. Applicants acknowledge that they contemplate conservative variations of SEQ ID NO: 1 (page 8, line 16) along with sequences that retain the same function as DAS5 (page 8, line 10). On page 29, beginning at line 4, Applicants describe detailed chemical properties of a DAS5 protein, including its

involvement in brassinosteroid synthesis. Table 1 on page 29 reports the chemical effects of overexpressing DAS5 on several components of the brassinosteroid synthetic pathway. For all of the above reasons, Applicants were in full possession of claims directed to the DAS5 protein or DAS5 gene.

However, solely to advance prosecution of the application, Applicants have amended independent Claims 1, 8 and 17 to recite plants, and methods of producing genetically modified plants, using a nucleic acid encoding a protein with at least 95% homology to SEQ ID NO. 1. Applicants note that the specification evidences that they were in full possession of sequences with at least 95% sequence identity to SEQ ID NO.1. For example, Applicants describe their use of sequence databases such as BLAST, or by PCR-related techniques, or by hybridization techniques (page 15, lines 3-12) to indicate their possession of sequences with at least 95% homology to SEQ ID NO: 1. The specification also describes methods to find similar sequences using, for example, hybridization techniques, as clearly described on page 15, line 12 through page 16, line 23.

For all of these reasons, Applicants were clearly in possession of sequences having at least 95% homology with SEQ ID NO: 1, as described in the specification at page 8, line 29. Accordingly, Applicants request the withdrawal of the written description rejection of Claims 1-5, 8, 12, 15-17, and 21.

Discussion of Enablement Rejections under 35 U.S.C § 112, First Paragraph

The Examiner rejected Claims 1-3, 5, 8, 12, 15-17, and 21 under 35 U.S.C. 112, first paragraph, alleging that the specification did not provide enablement for claims drawn to a method of producing a genetically modified plant, a genetically modified plant and genetically modified plant seed comprising transforming a plant with any nucleic acid encoding any DAS5 polypeptide or a DAS5 polypeptide exhibiting 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:1. Applicants respectfully traverse.

The test for enablement is defined in *In re Wands*, where the statute, 35 U.S.C. § 112, first paragraph, was interpreted to require that the claimed invention be enabled so that any

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person skilled in the art can make and use the claimed invention without undue experimentation. *See* 858 F. 2d at 737, 8 U.S.P.Q.2d at 1404 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *See* 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

It would not require undue experimentation to enable one of ordinary skill in the art to make and use the full scope of plants expressing DAS5 sequences without undue experimentation. For example, the specification describes how to use computer programs, such as BLAST to determine other sequences that have homology with the DAS5 protein (page 9, beginning on line 21). In addition, page 15, lines 3-11 describes a variety of methods for obtaining DAS5 polynucleotides including routine screening of genomic libraries and using antibodies to isolate expressed proteins corresponding to DAS5. Accordingly, while some experimentation may be required, it is not undue experimentation. For this reason, Applicants have fully enabled one to make and use DAS5 genes and proteins.

However, solely to advance prosecution of this application, Applicants have amended independent Claims 1, 8, and 17 to be drawn to plants, and methods of producing a genetically modified plants, that express an amino acid with 95% homology to SEQ ID NO. 1. Applicants clearly teach how to make and use sequences having at least 95% homology with SEQ ID NO: 1, as described in the specification at page 8, beginning on line 29. For example, as described in the specification, sequences with at least 95% homology can be determined from a BLAST search to determine homology, or through biochemical enrichment or purification procedures (page 9, lines 13-20).

The Examiner argues that it is unpredictable whether or not sequences having less than 100% identity with SEQ ID NO: 1 will function to make plants larger. However, the fact that some sequences will not function does not make the experimentation undue. In fact, the finding by the court in *In re Wands* was that Wands' "disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high

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level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.” Accordingly, the court found that Wands had fully enabled the broad scope of the invention.

A similar situation is found with this application in that Applicants’ application provides considerable guidance and working examples of producing plants that encode a DAS5 protein with 95% homology to SEQ ID NO: 1. See Example 1 on page 34. Moreover, Example 1 also provides guidance on how to screen thousands of plants at a time to determine which ones have increased growth. Thus, it would only take routine experimentation to determine whether a plant expressing a sequence with 95% homology to SEQ ID NO: 1 had increased growth. Such screening techniques are merely routine by one of ordinary skill in the art, and all of the methods needed to practice the invention are well known.

For all of the above reasons, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 112, and allowance of the pending application.

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CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,

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Dated: June 12, 2003

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